

Appl. No. : 10/616,102
Filed : July 9, 2003

SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

None

Identification of Claims Discussed

1 and 9

Identification of Prior Art Discussed

D'Antonio (U.S. Pat. No. 5,810,831).

Proposed Amendments

Applicants will amend at least one independent claim to further define the femur-size template.

Principal Arguments and Other Matters

Applicants respectfully submit D'Antonio does not teach, among other things, providing a femoral slideway that is undersized relative to the unresected femur, much less undersizing the femoral slideway by the particular percentages claimed. Applicants also argued that D'Antonio fails to teach a pre-determined distance defined by a template having a permanently specified distance between a bore and a contact surface of the template, the contact surface configured to engage at least one of the dorsalmost points of the lateral and medial condyles of the femur, as recited by amended Claim 1.

Results of Interview

Applicants agreed to amend the claims to further clarify the invention relative to D'Antonio.

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REMARKS

Upon entry of the foregoing amendment, Claims 1-23 remain pending in the above-identified application. Claims 1, 9, 16 and 18 have been amended and new Claims 22-23 have been added. In response to the Office Action mailed September 22, 2005, Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the following comments.

Specification

The Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. In particular, the Examiner noted that “the limitations of the ‘previously-determined distance’ being between ‘about 26.4 mm and about 37.44 mm’ or ‘about 32 mm’ or between ‘about 30.45mm and bout 33.35 mm’ was not found in the written disclosure.” The Examiner also noted that “[t]he use of the terms ‘about’ causes some ambiguity because it is not clear according to the disclosure how much of a deviation from the disclosed range the term ‘about’ is supposed to be interpreted with respect to the Applicants’ distance of components.”

Applicants have amended the specification, as noted above, to explicitly recite the dimensions “between 26.4 mm and 37.44 mm,” “about 32 mm” and “between 30.45 mm and 33.35 mm.” Applicants respectfully submit that no new matter has been added and that the amendment to the specification is fully supported by the non-limiting embodiments described in at least page 2, line 29 – page 3, line 15 of the specification (i.e. paragraphs [0008] and [0009] of the published application), as well as by originally filed Claims 13-15. Accordingly, Applicants respectfully request entry of the amendment to the specification and withdrawal of this objection.

Rejection of Claims Under 35 USC § 112

Claims 13 and 14 stand rejected under 35 USC § 112, ¶1, as failing to comply with the written description requirement. The Examiner asserts that the limitation in Claim 13 that the “previously-determined distance is between about 26.4 mm and about 37.4 mm” is not supported in the specification.

As discussed above, Applicants have amended the specification to explicitly recite a dimension between “26.44 mm and about 37.44 mm,” recited in amended Claim 13, and a dimension “about 32 mm,” recited in Claim 14. As noted above, Applicants respectfully submit

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that the amendment to the specification is fully supported by at least the non-limiting embodiments described in page 2, line 29 – page 3, line 15 of the specification (i.e., paragraphs [0008] and [0009] of the published application), and that no new matter has been added.

The Examiner asserts that the limitation in Claim 13 that the “previously-determined distance is between about 26.4 mm and about 37.4 mm” is not supported in the specification and that “[t]he written disclosure on page 3, line 12 provides support for *up to 34 mm*, but not beyond that.” The Examiner appears to point to the disclosed range of between 24 and 34 mm for the “distance between the dorsal sliding surface and the one or more pegs on the inside of the femoral slideway.” See page 3, lines 10-15 of the specification (i.e., published application, paragraph [0009]). However, the range “between 24 mm and 34 mm” identified by the Examiner does not refer to the dimensions recited in Claims 13-15.

Applicants, respectfully point out that the range of “between 24 mm and 34 mm” refers to the distance between the pegs and the dorsal sliding surface of the femoral slideway (i.e., femoral prosthesis illustrated in the non-limiting embodiments shown in Figures 1 and 2), not the distance between the bores and the contact surface of the femur-size template (i.e., template illustrated in the non-limiting embodiments shown in Figures 3 and 4). Claims 13-15 recite dimensions for a previously-determined distance that is defined in Claim 9 as the “location of a hole to be drilled in a lower surface of a femur bone [relative to] a dorsal-most point of a condyle of said femur,” and which is determined, in one non-limiting embodiment, by the distance between the bores on the femur-size template and the contact surface of the template. See page 3, lines 10-15 of the specification (i.e., published application, paragraph [0009]). This distance between the bores on the femur-size template and the contact surface of the template is “5-15%, in particular about 10%” larger than the distance separating one or more pegs on the femoral slideway from the dorsal sliding surface of the slideway (i.e., 5-15%, in particular about 10% larger than “the range between 24 and 34 mm, and in particular 29 mm”). See non-limiting embodiments described in page 2, line 29 – page 3, line 15 of the specification (i.e., paragraphs [0008] and [0009] of the published application).

Accordingly, Applicants respectfully request the withdrawal of this rejection.

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Rejection of the Claims Under 35 USC § 102

Claims 1, 2, 5, 6, 16, 18, and 19 stand rejected under 35 USC § 102(b) as being anticipated by D'Antonio (U.S. Patent No. 5,810,831). Applicants have amended Claim 1 and respectfully traverse the rejection of Claims 16, 18 and 19.

D'Antonio discloses a femoral sizing guide having a sizing guide block 22 that can be positioned adjacent a distal end 16 of a femur 10, from which a distal portion 14 has been removed. See '831 patent at Col. 4, lines 1-10. The guide also has locator feet 26 for engaging the posterior condyles 30 to assist in the location of a femoral cutting guide of suitable size. See '831 patent at Col. 4, lines 18-42; Figure 1. The guide block 22 has drill guide openings 60 to guide a drill 62, "thereby assuring the appropriate subsequent location of the femoral cutting guide on the distal femur." '831 patent at Col. 4, lines 57-62. The locator feet 26 can be chosen from a variety of sizes to "space the openings 60 in the sizing guide block 22, in the anterior/posterior direction, by a corresponding selected amount." '831 patent at Col. 5, lines 12-35.

However, D'Antonio does not disclose, teach or suggest, among other things, a "pre-determined distance determined by a template having a permanently specified distance between a bore and a contact surface of the template, the contact surface configured to engage at least one of the dorsalmost points of the lateral and medial condyles of the femur," as recited by Claim 1 as amended. As described above, the femoral sizing guide of D'Antonio has removable and replaceable locator feet, and therefore, cannot specify a permanent distance.

Similarly, Applicants have amended Claim 16 to recite "providing at least one hole in said femur to receive said at least one peg of said slideway and to secure and locate said slideway on said femur, the position of said at least one hole being a pre-determined distance from a plane tangent to dorsalmost points of lateral and medial condyles of the femur, the pre-determined distance defined by a femur-size template having a permanently specified distance between a bore and a contact surface of the template, the contact surface configured to engage at least one of the dorsalmost points of the lateral and medial condyles of the femur," which Applicants respectfully submit is not disclosed in D'Antonio, as discussed further below.

Furthermore, as discussed at the interview, D'Antonio fails to teach or suggest the undersizing of the femoral slideway relative to the unresected femur, as recited in amended Claims 1 and 16.

Figure 4 of Applicant's specification illustrates one non-limiting embodiment, reproduced below, wherein a femur-size template is used to locate the previously-determined distance "e" from a peg-hole and condyles of an unresected femoral bone.

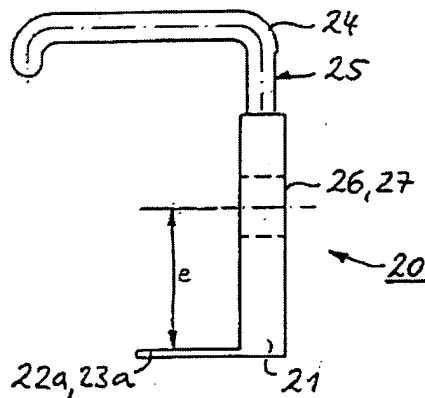
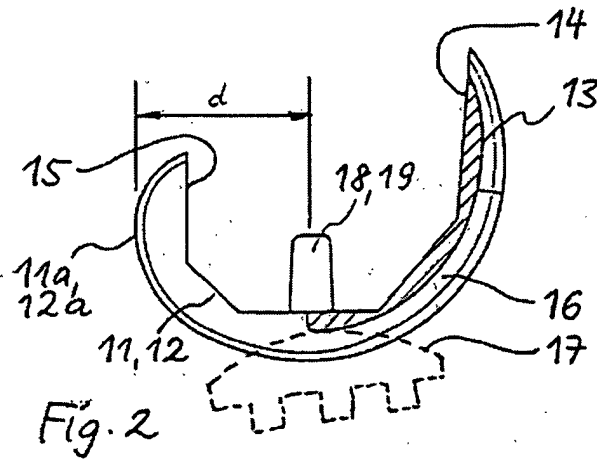
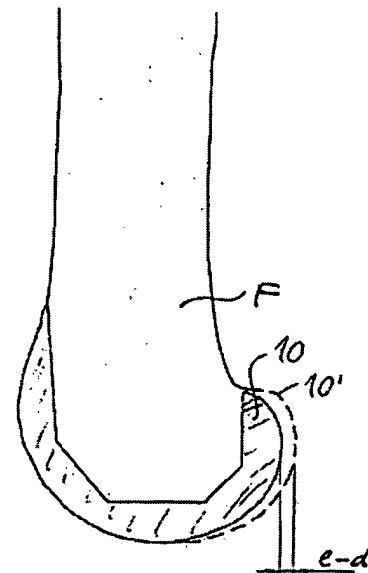


Fig. 4

Once the peg-hole is drilled through a bore (26, 27) based on the previously determined distance "e" between the bore (26, 27) and contact surfaces (22a, 23a) of the template that engage the unresected condyles of the femur, a slideway, such as shown in Figure 2, is selected, which has a distance "d" defined between the outermost posterior points on the distal sliding surfaces (11a, 12a) and the long axis of the pegs (18, 19). The distance "e" between the bores (26, 27) and the contact surfaces (22a, 23a) is not adjustable, nor are the contact surfaces (22a, 23a) detachable from the femur-size template or adjustable to accommodate variations in femur anatomy.



This slideway is selected such that the distance "e" is greater than the distance "d", indicating that more bone has been resected dorsally on the femur than will be replaced by the thickness of the dorsal parts of the condyle shells, as shown in Figure 5b below. As described in the non-limiting embodiment on page 2, line 29 – page 3, line 9 of the specification, the distance "e" can be greater than the distance "d" by 5-15%, and in particular by about 10%. Moreover, because the peg-hole location was predetermined by use of the femur-size template, the slideway's position is also predetermined relative to the original, unresected femur.



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Accordingly, Applicants respectfully submit that amended Claims 1 and 16 are allowable over D'Antonio. Claims 2, 5, and 6 depend from amended Claim 1 and are therefore also allowable over D'Antonio for at least the same reasons as amended Claim 1. Applicants have amended Claim 18 to provide correct antecedent basis for the "femur-size template" in view of the amendment to Claim 16. Claims 18 and 19 depend from Claim 16 and are therefore also allowable over D'Antonio for at least the same reasons as Claim 16.

Rejection of the Claims Under 35 USC § 103

Rejections in view of D'Antonio

Claims 3, 4, 7, 9-15, 17, 20, and 21 stand rejected under 35 USC § 103(a) as being unpatentable over D'Antonio. Applicants respectfully traverse the rejection of Claims 9-15, 17, 20 and 21.

Claims 3, 4 and 7

Applicants respectfully submit that amended Claim 1 is patentable over D'Antonio because D'Antonio does not teach or suggest, among other things, a "pre-determined distance determined by a template having a permanently specified distance between a bore and a contact surface of the template, the contact surface configured to engage at least one of the dorsalmost points of the lateral and medial condyles of the femur," as recited in amended Claim 1. Claims 3, 4, depend from Claim 1 and are therefore also allowable over D'Antonio, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught in the cited art.

Claims 9-15, 17, 20, 21

Applicants respectfully submit that D'Antonio does not disclose, teach or suggest, among other things, "resecting bone material from said femur, wherein resecting includes removing more bone material from a dorsal side of the femur than will be replaced by the slideway," as recited in amended Claim 9 and discussed above. (emphasis added) Moreover, D'Antonio does not disclose "indicating a point at a previously-determined distance from a dorsal most point of said femur, wherein said previously-determined distance is 5 to 15% larger than a distance between a peg and a dorsal sliding surface of the femoral slideway to be implanted on the femur bone," as recited in amended Claim 9. Without D'Antonio teaching these desired features, it would not have been merely a matter of design choice for the previously-determined distance to

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be 5 to 15% larger than a distance between a peg and a dorsal sliding surface of the femoral slideway.

D'Antonio fails to teach or suggest the unique features described above, and in particular, those recited in amended Claim 9. For the reasons discussed above, Applicants respectfully submit that amended Claim 9 is patentable over D'Antonio. Applicant has amended Claim 15 to recite that the previously-determined distance is between 30.45 mm and 33.35 mm, which is supported by at least page 2, line 29 – page 3, line 15 of the specification (i.e. paragraphs [0008] and [0009] of the published application), as discussed above. Claims 10-15 depend from amended Claim 9 and are therefore likewise patentable over D'Antonio, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught in the cited art.

Claims 17, 20 and 21

Applicants respectfully submit that amended Claim 16 is patentable over D'Antonio because D'Antonio does not teach or suggest, among other things, “resecting bone material from a femur, wherein said resecting includes removing more bone material from a dorsal side of the femur than is replaced by the slideway.” Additionally, Applicants respectfully submit that D'Antonio does not teach or suggest, among other things, “providing at least one hole in said femur to receive said at least one peg of said slideway and to secure and locate said slideway on said femur, the position of said at least one hole being a pre-determined distance from a plane tangent to dorsalmost points of lateral and medial condyles of the femur, the pre-determined distance defined by a femur-size template having a permanently specified distance between a bore and a contact surface of the template, the contact surface configured to engage at least one of the dorsalmost points of the lateral and medial condyles of the femur.” As discussed above, D'Antonio discloses a sizing template with a plurality of removable locator feet that define a variable distance between the contact surface of the locator feet and the bores on the sizing template. In contrast, as illustrated in the non-limiting embodiment of Figure 4, reproduced above, the distance between the bore (26, 27) and the contact surface (22a, 23a) on the femur-size template is not adjustable. Additionally, the femur-size template shown in Figure 4 does not allow for the compensation of variations in femur anatomy since the contact surfaces (22a, 23a) are not detachable from the femur-size template.

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Claims 17, 20 and 21, depend from amended Claim 16 and are therefore also patentable over D'Antonio, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught in the cited art.

Rejection in view of D'Antonio and Colleran

Claim 8

Claim 8 stands rejected under 35 USC § 103(a) as being unpatentable over D'Antonio in view of Colleran (U.S. Pat. No. 5,776,201).

As discussed above, Applicants respectfully submit that amended Claim 1 is patentable over D'Antonio because D'Antonio does not teach or suggest, among other things, a "pre-determined distance determined by a template having a permanently specified distance between a bore and a contact surface of a unitary part of the template, the contact surface configured to engage at least one of the dorsalmost points of the lateral and medial condyles of the femur," as recited in amended Claim 1.

Claim 8 depends from Claim 1 and is therefore likewise patentable over D'Antonio, alone or in combination with the cited references, not only because it depends from an allowable base claim, but also because it recites a unique combination of features not taught in the cited art. For example, Claim 8 recites, among other limitations, that "all of the slideways in said group have substantially equal peg-to-sliding surface dimensions as defined by a perpendicular distance between a longitudinal axis of a peg extending from the slideway and a plane tangent to a dorsal sliding surface furthest away from the peg, each slideway in said group has a different dorsal condyle-to-ventral condyle distance." Colleran, alone or in combination with D'Antonio, fails to teach these features. In particular, Colleran at most teaches femoral implants with different anterior-posterior lengths. See Colleran, Col. 2, lines 54-67. However, Colleran does not teach or suggest a group of slideways, wherein all of the slideways in the group have substantially equal peg-to-sliding surface dimensions, each slideway in said group having a different dorsal condyle-to-ventral condyle distance. The peg-to-sliding surface dimension is illustrated in the non-limiting embodiment shown in Figure 2 of Applicant's specification as a distance "d," whereas the dorsal condyle-to-ventral condyle distance is illustrated in the non-limiting embodiment shown in Figure 1 of Applicant's specification as a distance "a."

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New Claims

Applicants have added new Claims 22 and 23. Claim 22 recites that the bore and contact surface are defined on a unitary part of the template. Claim 23 recites that the previously-determined distance is 5 to 15% larger than the distance between the peg and the dorsal sliding surface of the femoral slideway to be implanted on the femur bone. Applicants respectfully submit that new Claims 22 and 23 are likewise patentable over D'Antonio, alone or in combination with the cited art, not only because these claims depend from allowable base claims, but also because each of these claims recites a unique combination of features not taught or suggested in the cited art.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Applicants also have not presented arguments concerning whether the applied references can be properly combined in view of the clearly missing elements noted above, and Applicants reserve the right to later contest whether a proper motivation and suggestion exists to combine these references.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney in order to resolve such issue promptly.

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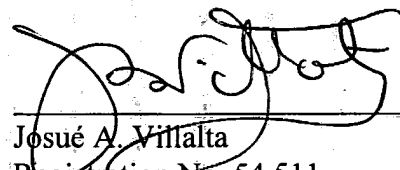
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2/21/06

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AMEND

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